No. 15-56808

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

DR. MELISSA STRAFFORD, CAROL JACQUEZ, and DAVID MATTHEWS, JR., individually and on behalf of all other persons similarly situated,

Plaintiffs-Appellants,

v.

ELI LILLY AND COMPANY, an Indiana Corporation,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
CASE NO. 2:12-CV-9366-SVW-MAN

OPENING BRIEF OF PLAINTIFFS-APPELLANTS

Michael L. Baum
Bijan Esfandiari
R. Brent Wisner
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Telephone: (310) 207-3233
Facsimile: (310) 207-4204

Michael Woerner
Alison S. Gaffney
KELLER ROHRBACK L.L.P.
1201 Third Avenue, Suite 3200
Seattle, WA 98101-3052
Telephone: (206) 623-1900
Facsimile: (206) 623-3384

Counsel for Plaintiffs-Appellants

****Additional Counsel for Plaintiffs-Appellants on following page***

Juli E. Farris
Khesraw Karmand
KELLER ROHRBACK L.L.P.
1129 State Street, Suite 8
Santa Barbara, CA 93101
Tel.: (805) 456-1496
Fax: (805) 456-1497

Mark D. Samson
KELLER ROHRBACK L.L.P.
3101 N. Central Avenue, Suite 1400
Phoenix, AZ 85012
Tel.: (602) 248-0088
Fax: (602) 248-2822

Samuel S. Deskin
DESKIN LAW FIRM, PLC
16944 Ventura Blvd
Encino, CA 91316
Tel.: (800) 709-8978
Fax: (800) 709-8971

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INTRODUCTION

Plaintiffs-Appellants Dr. Melissa Strafford, Carol Jacquez, and David Matthews, Jr. ("Plaintiffs") allege Defendant-Appellee Eli Lilly and Company ("Lilly") misrepresented and omitted material information about the risks of withdrawal upon stopping treatment with the prescription drug Cymbalta. Although Lilly disclosed to European consumers that the withdrawal risk was at least 45% and that withdrawal could last for months, Lilly never so told American consumers (or doctors). Instead, the American label only stated that certain withdrawal symptoms occurred at a rate "greater than or equal to 1%." By minimizing the serious risk of long-lasting withdrawal in its promotion of Cymbalta, Lilly violated the consumer protection laws of California, Massachusetts, Missouri, and New York.

But in a series of written orders, the district court rendered these consumer protection laws impotent as to pharmaceutical products. The district court held that (1) consumers lack standing to enjoin ongoing deceptive conduct, (2) pharmaceutical manufacturers are not legally accountable for what they tell consumers, and (3) consumer class actions are never possible for prescription drugs because they are sold

in an inefficient market in which damages are difficult to estimate. These holdings are based on legal and factual errors and, together with the district court's procedural mismanagement of the case, warrant reversal.

STATEMENT OF JURISDICTION

I. The District Court Had Original Jurisdiction.

The district court had jurisdiction under 28 U.S.C. § 1332(d)(2) because this is a proposed class action in which at least one member of the classes is a citizen of a state different from Lilly and the matter in controversy exceeds $5,000,000.

II. This Court Has Appellate Jurisdiction.

This Court has jurisdiction pursuant to 28 U.S.C. § 1291 as this is an appeal from a final judgment. The district court dismissed Plaintiffs' claims with prejudice, granting Plaintiffs' motion for voluntary dismissal. ER1. "[V]oluntary dismissals with prejudice that produce an adverse final judgment may be appealed." *Ward v. Apple Inc.*, 791 F.3d 1041, 1045 (9th Cir. 2015); *e.g.*, *Berger v. Home Depot USA, Inc.*, 741 F.3d 1061, 1065 (9th Cir. 2014). A dismissal with prejudice, like that entered by the district court, "is tantamount to a judgment on the

merits." *Zenith Ins. Co. v. Breslaw*, 108 F.3d 205, 207 (9th Cir. 1997) (citation omitted).

The district court entered final judgment on October 26, 2015. ER1-4. Plaintiffs' notice of appeal was timely filed on November 23, 2015. ER63-67.

ISSUES PRESENTED

1. Do consumers who continue to purchase Cymbalta have standing to seek injunctive relief to change Cymbalta's deceptive label?

2. Does the learned intermediary defense, an affirmative defense to failure-to-warn tort claims, apply to claims brought under state consumer protection statutes?

3. Did the district court abuse its discretion by ordering Plaintiffs to oppose summary judgment and move for class certification without allowing discovery?

4. Did the district court abuse its discretion by denying class certification under Federal Rule of Civil Procedure ("Rule") 23(b)(3) when Plaintiffs presented a classwide damages model consistent with their theory of liability?

5. Did the district court abuse its discretion by denying class certification under Rule 23(b)(3) when Plaintiffs sought only statutory damages pursuant to New York and Massachusetts statutes?

6. Did the district court abuse its discretion by denying class certification under Rule 23(c)(4) despite having previously identified a common issue at the heart of this case?

7. Did the district court abuse its discretion by denying Plaintiffs' motion for sanctions without explanation?

STATEMENT OF THE CASE

I. Lilly Omitted the True Withdrawal Risk of Cymbalta.

Cymbalta is an antidepressant used to treat psychiatric and chronic pain conditions. ER117. It was first approved by the FDA in 2004 and quickly grew to be one of the most successful antidepressants ever. ER117. For years, consumers heard Cymbalta's catchy marketing slogan: "Depression hurts. Cymbalta can help." What they did not hear was how difficult it can be to quit Cymbalta once started.

Specifically, Lilly did not disclose the frequency, severity, or duration of Cymbalta withdrawal in its marketing or on the label. By

omitting this material information from Cymbalta's marketing and labeling, Lilly was able to sell more product.

Before Cymbalta entered the market in 2004, Lilly's clinical data revealed that a large percentage of Cymbalta consumers who stopped taking it suffered serious withdrawal symptoms. ER121. Lilly's data showed that at least *44% of consumers* who stopped taking Cymbalta in double-blind placebo-controlled trials **spontaneously**[1] reported withdrawal symptoms. ER121. For consumers who stopped Cymbalta after an open-label trial lasting a year—which most approximates a typical consumer's experience—*over 50%* spontaneously reported withdrawal symptoms. ER121. In both short-term and long-term trials, over half the people reporting withdrawal were still experiencing symptoms beyond two weeks after the trials ended, and the majority of those symptoms were moderate or severe. ER496-97.

But Lilly did not disclose these risks to American consumers in its marketing or labeling of Cymbalta. ER119-22. Instead, the Cymbalta

[1] Use of "spontaneously" is deliberate. Lilly researchers did not use a systematic checklist for measuring withdrawal symptoms during its trials, instead relying on voluntary reports from participants. Lilly researchers acknowledge that use of a symptom checklist would have resulted in higher incident rates. ER499.

label misleadingly portrayed withdrawal as rare, mild, and short-lived. *Id.* Rather than disclosing the 44% or 50% risk reported in Lilly's trials, the American label lists only discrete symptoms occurring "at a rate greater than or equal" to 1% or 2%. ER119. In contrast, the European Cymbalta label, in addition to providing the list of discrete symptoms, states that the risk of withdrawal is 45% and that symptoms may last "2-3 months or more." ER288.

Lilly deliberately downplayed these risks in the U.S. to increase sales. ER109-10, 148. Documents show that prior to Cymbalta's launch Lilly knew that low withdrawal risk was an attribute valued in the marketplace. For example, in 2002, Lilly commissioned a "U.S. Strategic Pricing Study for Cymbalta," which found that "[m]inimization of withdrawal syndrome is seen as important" and that "[a] significant decrease in rate and severity of withdrawal / discontinuation syndrome" "could justify or warrant consideration of premium pricing relative to EffexorXR"—the primary competitor of Cymbalta. ER255, 260.

Lilly's failure to disclose material information violated the consumer protection laws of California, Massachusetts, Missouri, and

New York.[2] ER143-57. Each named Plaintiff believed, based on Lilly's representations, that withdrawal from Cymbalta was infrequent, mild, and short-lived. ER110-14. Accordingly, Plaintiffs sought injunctive relief and damages for the money they spent out of pocket on Cymbalta. ER158-59.

II. The District Court Ordered Motions for Summary Judgment and Class Certification Without Allowing Discovery.

Plaintiffs filed suit in October 2012, and Lilly thereafter moved to dismiss. The district court held that Plaintiffs lacked Article III standing to bring claims for declaratory and injunctive relief, but denied the rest of the motion. ER50-62.

[2] Plaintiff Jacquez is a resident of California, Plaintiff Matthews is a resident of Missouri, and Plaintiff Strafford is a resident of New York, but was a resident of Massachusetts when she first purchased Cymbalta. Plaintiffs alleged claims under California's Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code §§ 1750, *et seq*., False Advertising Law ("FAL"), Cal. Bus. & Prof. Code §§ 17500, *et seq*., and Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq*.; Massachusetts's Consumer Protection Act ("Ch. 93A"), Mass. Gen. Laws ch. 93A, §§ 1, *et seq*.; Missouri's Merchandising Practices Act ("MPA"), Mo. Rev. Stat. §§ 407.010, *et seq*.; and New York's Consumer Protection from Deceptive Acts and Practices Law ("NYCPA"), N.Y. Gen. Bus. Law §§ 349, *et seq*.

During argument, the district court invited Lilly to file a motion for summary judgment. ER502-03. In response, Plaintiffs requested that discovery be opened to oppose summary judgment. ER504. The court denied Plaintiffs' request and instead instructed Plaintiffs to file a Rule 56(d) motion as needed. ER504.

In March 2013, Lilly moved for summary judgment. In response, Plaintiffs filed a Rule 56(d) motion requesting discovery to oppose Lilly's motion. Rather than allow discovery, the district court ordered Plaintiffs to oppose summary judgment solely on whether the learned intermediary defense applies to consumer protection claims. ER48-49.

III. The Parties Completed Lengthy Motion Practice on Class Certification, Still Without Discovery.

In June 2013, the district court ruled that the learned intermediary defense applied to consumer protection statutes. ER43. The Court held that "[i]n order to prevail on its defense, Defendant must establish that it adequately warned prescribing physicians of the effects of Cymbalta withdrawal." ER43. Since "the question of whether a warning was adequate is a question of fact. . . . [P]laintiffs are entitled

to additional discovery necessary to demonstrate whether the warnings provided in this case were 'adequate.'"[3] ER43.

Despite those statements, the district court did not enter a scheduling order or open discovery. Instead, it *sua sponte* raised the issue of class certification and questioned whether class actions were *ever* viable in prescription drug cases. ER44. The Court mused that "[a]lthough the question of whether or not the warnings given to doctors, and consumers, were inadequate or misleading ***may be capable of resolution on a class-wide basis***, the question of whether or not, had the warnings been adequate, each plaintiff would not have taken Cymbalta [is] not." ER44 (emphasis added). The district court then ordered Plaintiffs to move for class certification—still without discovery, initial disclosures, a case management order, or an answer to the complaint. ER45.

Plaintiffs accordingly filed two motions for class certification in August 2013. The first sought certification of damages classes under Rule 23(b)(3) for consumers in California, Massachusetts, Missouri, and

[3] At this time, there had been no discovery. The district court's use of the phrase "additional discovery" is therefore incorrect.

New York. The second sought certification of issue-only classes under Rule 23(c)(4) and, for the purposes of preserving the issue, injunctive relief classes under Rule 23(b)(2). The second motion focused on the issue that the Court identified as capable of classwide resolution, i.e., "whether or not the warnings given to doctors, and consumers, were inadequate or misleading." ER44.

The motions were accompanied by declarations from the named Plaintiffs and four experts. One expert was Joel W. Hay, Ph.D., an economist at the University of Southern California's School of Pharmacy. Dr. Hay offered testimony about methods he could use to estimate damages for the class, including a proposal to estimate the difference in value between Cymbalta as represented (low withdrawal risk) and Cymbalta as sold (significant withdrawal risk). ER383-90.

Lilly filed oppositions to class certification without any expert rebuttal. At the hearing, the district court challenged Lilly for not submitting any evidentiary support and ordered Lilly "to submit a supplemental brief with accompanying exhibits that describes the evidentiary support for its position." ER373-74; ER37. Lilly's supplemental brief included several expert declarations. None, however,

criticized or responded to Dr. Hay's proposed damages model. Plaintiffs filed a response, including a second declaration from Dr. Hay and examples of Lilly's use of the same method as Dr. Hay's. ER305-69.

On November 4, 2013, the district court held another hearing on class certification, during which it asked Lilly why it did not challenge Dr. Hay's methodology and whether Lilly's use of Dr. Hay's methodology meant Lilly was "hoisted by your own petard." ER303. Lilly indicated that it could dispute the methodology, so the district court gave Lilly another opportunity to supplement and ordered the parties to file a third round of briefing. ER36.

IV. The District Court Allowed Narrow Discovery on Lilly's Request.

Because discovery was not open, Lilly requested permission to conduct discovery and depose Dr. Hay. ER304. Although the district court had repeatedly refused to open discovery at Plaintiffs' request, the district court granted Lilly's request. ER304. The district court ordered the parties to "meet and confer and attempt to reach agreement over exchanging information necessary to brief these issues efficiently." ER36.

On November 11, 2013, Plaintiffs sent Lilly ten requests for production and one interrogatory relating to Lilly's use of the same methodology as Dr. Hay. ER610-11. On December 13, 2013, Lilly indicated that it would not respond to Plaintiffs' requests and, as "an accommodation," produced five examples of Lilly's use of the methodology. ER638.

Because Lilly declined to fully respond to Plaintiffs' requests, Plaintiffs filed a motion to compel. The district court granted the motion in part. ER33-34. A month later, Lilly produced four additional documents.

V. The District Court Rejected Plaintiffs' Motions for Class Certification.

On December 18, 2014, the district court denied Plaintiffs' motions for certification under Rule 23(b)(3) and (c)(4). ER15-32.

Plaintiffs thereafter filed a Rule 23(f) petition with this Court on January 2, 2015. On March 25, 2015, this Court denied Plaintiffs' petition. ER14.

In June 2015, Plaintiffs filed a third motion for class certification, limited to classes of Massachusetts and New York consumers seeking statutory damages only, which are permitted in lieu of actual damages.

Mass. Gen. Laws ch. 93A, § 9(3); N.Y. Gen. Bus. Law § 349(h). The district court denied the motion. ER7-13.

VI. Plaintiffs Voluntarily Dismissed Their Claims and Filed This Appeal.

On September 30, 2015, Plaintiffs filed a motion to voluntarily dismiss their claims to allow an appeal. On October 26, 2015, the district court granted Plaintiffs' motion over Lilly's opposition and dismissed this matter with prejudice. ER1-4. On November 23, 2015, Plaintiffs filed a timely notice of appeal. ER63-67.

SUMMARY OF THE ARGUMENT

At the outset, the district court held that Plaintiffs lacked standing to seek injunctive relief for two reasons: (1) they did not intend to purchase Cymbalta in the future and (2) they were now aware of Lilly's deception. To address the first reason, Plaintiffs requested leave to amend to add a plaintiff still purchasing Cymbalta, but the district court ignored Plaintiffs' request. The district court's second rationale creates a Catch-22: the moment a consumer discovers Lilly's deception, she no longer has standing to stop it. Article III does not require this absurd result. Standing to seek injunctive relief turns on redressability, and injunctive relief is what redresses the statutory injury, namely,

Lilly's ongoing dissemination of misleading information about the serious risk of Cymbalta withdrawal.

In inviting Lilly to move for summary judgment to determine whether the learned intermediary defense ("LID") barred recovery, the district court erred. Procedurally, the district court did not give Plaintiffs an opportunity to conduct discovery to oppose summary judgment. Substantively, the LID is an affirmative defense to failure-to-warn tort claims and is not an element of the state consumer protection statutes.

In its ruling, the district court held that the supreme courts of California, Massachusetts, Missouri, and New York would apply the LID to their respective consumer protection statutes. This was incorrect for three reasons: (1) the justifications for the LID no longer hold true in the modern medical landscape, (2) there is no statutory basis for incorporating a tort defense into remedial statutes intended to have reach beyond common law causes of action, and (3) there was no analysis of the statutes or state law.

The district court next ordered Plaintiffs to move for class certification without discovery, an abuse of discretion, especially given

that the court later denied class certification in part because Plaintiffs supposedly had not put forth sufficient evidence. Although Plaintiffs moved to certify classes in three different ways—23(b)(3) classes seeking actual damages, 23(b)(3) classes seeking statutory damages, and liability-only classes under 23(c)(4)—the district court rejected each one. Its rulings were based on legal and factual errors and together contradicted the purpose of Rule 23. With respect to the proposed classes seeking actual damages, the district court erred in several ways:

- going beyond the inquiry required at class certification and improperly considering the merits of Plaintiffs' damages model,
- concluding damages could not be determined in an inefficient market,
- failing to fully consider how Plaintiffs' damages model could estimate damages,
- improperly taking sides in a factual dispute between experts,
- ruling, based on a misunderstanding of the statutes, that Plaintiffs' damages model was not tied to their liability theory,

- applying the wrong causation standard, and
- ruling that individualized damage calculations could defeat certification under Rule 23(b)(3).

In addition, the district court abused its discretion by denying classes seeking statutory damages, notwithstanding that Plaintiffs can establish statutory harm through common proof. The district court also abused its discretion by holding that inability to determine classwide damages precluded certification of a *liability-only* issue class under Rule 23(c)(4), essentially rendering that rule a nullity.

Last, the district court erred by refusing to make factual findings and impose sanctions for Lilly's discovery misconduct. Although the district court allowed only narrow discovery, Lilly nevertheless withheld documents that were highly relevant to the multiple rounds of motion practice on Plaintiffs' class damages model.

Whether Lilly misled millions of consumers by downplaying the serious withdrawal risk associated with Cymbalta deserves adjudication. Rule 23 exists so that cases like this one—in which many people have been harmed by a common course of conduct, but not enough to justify individual litigation—can be heard. Without the

barriers erected by the district court's numerous errors, Plaintiffs' claims satisfy the requirements of Rule 23(b)(2), (b)(3), and (c)(4).

ARGUMENT

I. Standards of Review

Determinations of standing are reviewed de novo. *Hajro v. U.S. Citizenship & Immigration Servs.*, 811 F.3d 1086, 1098 (9th Cir. 2016). A district court's determination of state law is also reviewed de novo. *Salve Regina Coll. v. Russell*, 499 U.S. 225, 231 (1991).

Denial of class certification is reviewed "for abuse of discretion" and the court "considers 'whether the district court correctly selected and applied Rule 23's criteria.'" *Edwards v. First Am. Corp.*, 798 F.3d 1172, 1177 (9th Cir. 2015) (citation omitted). Any "underlying legal questions, however, are reviewed *de novo,* and 'any error of law on which a certification order rests is deemed a per se abuse of discretion.'" *Id.* (citation omitted).

Rulings on discovery sanctions are generally reviewed for an abuse of discretion. *Halaco Eng'g Co. v. Costle*, 843 F.2d 376, 379 (9th Cir. 1988). If, however, the district court fails to make factual findings regarding the requested sanction, the decision is reviewed de novo. *See*

Fonseca v. Sysco Food Servs. of Ariz., Inc., 374 F.3d 840, 845-46 (9th Cir. 2004).

II. The District Court Erred By Holding That Plaintiffs Did Not Have Standing To Seek Injunctive Relief.

On Lilly's motion to dismiss, the district court held that Plaintiffs lacked Article III standing to seek injunctive relief for two reasons: first, that Plaintiffs "failed to allege that they intend to purchase Cymbalta in the future," and second, that "even if they did, they now know about the possibility of the side-effects." ER62.

With respect to the first point, the district court abused its discretion by ignoring Plaintiffs' request to amend and add a named plaintiff who continues to purchase Cymbalta.

But the district court's second reason is an error of law. Article III does not mandate this unjust result, under which ***no one*** would have standing to seek injunctive relief for deceptive advertising because a consumer's awareness of the deception would strip him of standing to try to stop it. Article III is meant to ensure that the plaintiff is the right individual to bring the issue to court, not to create a Catch-22.

A. The district court abused its discretion in ignoring Plaintiffs' request to add a class representative who continues to purchase Cymbalta.

Because some people are afraid to stop taking Cymbalta due to its withdrawal effects, or resumed taking Cymbalta to relieve their withdrawal symptoms, there are class members who continue to take Cymbalta. Thus, the district court should have granted Plaintiffs leave to amend to add a named plaintiff who continues to purchase Cymbalta and could represent a (b)(2) class. *See* ER454; ER376-77. Instead, the district court ignored Plaintiffs' request, a per se abuse of discretion. *See* ER30-31; *Miller v. Hambrick*, 905 F.2d 259, 262 (9th Cir. 1990) ("A district court's failure to exercise discretion constitutes an abuse of discretion.").

B. Injunctive relief redresses ongoing statutory injury.

To establish Article III standing, a plaintiff must show injury in fact, causation, and redressability. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Standing to seek prospective injunctive relief—the issue here—turns on the last of these, redressability. That is because "the claimed threat of injury must be likely to be redressed by the prospective injunctive relief." *Ellis v. Costco Wholesale Corp.*, 657 F.3d

970, 979 (9th Cir. 2011). This is the concern underlying the district court's ruling that Plaintiffs cannot seek injunctive relief because they "now know" of Lilly's deception. *See Ries v. Ariz. Beverages USA LLC*, 287 F.R.D. 523, 533 (N.D. Cal. 2012) (the argument that "plaintiffs are not threatened by future harm because they are now aware of [the alleged deception], and can no longer be deceived . . . is best understood as an argument directed to redressability"). By misconceiving the future harm, the district court did not recognize that injunctive relief will provide redress.

This is a consumer protection case, in which the injury is a creature of statute. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016) ("'Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before.'") (quoting *Lujan*, 504 U.S. at 580).[4] The Article III injury-in-fact is therefore the deceptive conduct prohibited by statute—i.e., the omission/misrepresentation of material information about Cymbalta. *Id.* at 1554-55 (citing cases in which plaintiffs' injury was the

[4] Likewise, state laws can create interests that support standing in federal court. *See Cantrell v. City of Long Beach*, 241 F.3d 674, 684 (9th Cir. 2001).

failure to obtain information to which they had statutory rights); *see also, e.g.*, *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 373 (1982) (in context of "racial steering" and housing discrimination, statute "establishe[d] an enforceable right to truthful information concerning the availability of housing"). Lilly's omission subjected consumers to an increased risk of withdrawal symptoms, and an increased risk of harm is injury-in-fact under Article III. *See Spokeo*, 136 S. Ct. at 1549; *Krottner v. Starbucks Corp.*, 628 F.3d 1139, 1143 (9th Cir. 2010). The future harm to be enjoined is Lilly's ongoing dissemination of misleading information in violation of state consumer protection law.

Where exposure to illegal conduct is accompanied by "any continuing, present adverse effects," there is "a present case or controversy regarding injunctive relief." *O'Shea v. Littleton*, 414 U.S. 488, 495-96 (1974). Because Lilly has not corrected its omission of material information about Cymbalta withdrawal, class members who purchase Cymbalta continue to be exposed to Lilly's deceptive conduct. For these class members, injunctive relief would provide redress to the statutory injury. Indeed, "[i]t can scarcely be doubted that, for a plaintiff who is injured or faces the threat of future injury due to illegal

conduct ongoing at the time of suit, a sanction that effectively abates that conduct and prevents its recurrence provides a form of redress." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185-86 (2000). Injunctive relief requiring revised promotional materials would redress the ongoing statutory injury by restoring the honest marketplace to which class members have a statutory right. As one court explained, "[p]laintiffs seek to be relieved from defendants' misleading and deceptive practices in the future, and the fact that they discovered the alleged deception years ago does not render defendants' advertising or labeling any more accurate or truthful." *Ackerman v. Coca-Cola Co.*, No. 09-395, 2013 WL 7044866, at *15 n.23 (E.D.N.Y. July 18, 2013). After all, "[t]his is the harm New York's and California's consumer protection statutes are designed to redress." *Id.*

Because Lilly has not corrected its ongoing deception regarding Cymbalta's withdrawal risk, this case is fundamentally different from those in which this Court held plaintiffs lacked standing to seek injunctive relief. *See Gest v. Bradbury*, 443 F.3d 1177, 1181-82 (9th Cir. 2006) (after defendant addressed offending conduct, plaintiffs sought a prohibition of "currently nonexistent" rules to future petitions); *Perez v.*

Nidek Co., 711 F.3d 1109, 1114 (9th Cir. 2013) (plaintiffs sought to enjoin defendants from engaging in illegal conduct, but alleged conduct ceased long before plaintiffs filed suit). Here, Lilly vigorously claims its portrayal of the risk is adequate. *See, e.g.*, ER69, 73-75. Prospective relief is not only appropriate, it is necessary.

Although each state's consumer protection law promises Plaintiffs an honest marketplace— "a health care market free from fraud and deception"[5]—Lilly's ongoing conduct denies Plaintiffs and all class members that right. A class member who continues to purchase Cymbalta experiences ongoing harm in a concrete and particularized way and has Article III standing to seek injunctive relief. Contrary to the district court's ruling, standing for these class members is not stripped away by awareness of the deception. Such a result is irrational and nothing more than a "draconic interpretation of the redressability requirement that is justified by neither precedent nor principle." *Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982). Article III's threshold requirements do not mandate such an outcome.

[5] ER470.

III. The District Court Erred In Applying the Learned Intermediary Defense to Consumer Protection Statutes.

The district court erred as a matter of law by holding that the learned intermediary defense ("LID") applies to Plaintiffs' claims under the consumer protection statutes of California, Massachusetts, Missouri, and New York. ER40-43. The LID is an affirmative defense to a failure-to-warn claim in tort, by which a prescription drug manufacturer fulfills its duty to warn consumers by warning the prescribing physicians.[6] The LID originated decades ago as an exception to the tort rule that a manufacturer must warn the ultimate consumer of any risks accompanying its product, because drug companies could not communicate directly with the consumers of their products.

Now, however, drug companies communicate directly with consumers through extensive advertising, and consumers actively research treatment decisions. Moreover, there is no statutory basis for importing a tort defense into these independent, remedial consumer

[6] *See, e.g.*, *Motus v. Pfizer Inc.*, 196 F. Supp. 2d 984, 990 (C.D. Cal. 2001) (discussing LID under California law), *aff'd sub nom. Motus v. Pfizer Inc., (Roerig Div.)*, 358 F.3d 659 (9th Cir. 2004).

statutes. And the district court failed to consider each state's law when predicting how the supreme court of each state would rule.

A. Justifications for the learned intermediary defense no longer exist.

Since the development of the LID as an affirmative defense in the 1960s and 1970s, the healthcare industry has changed dramatically. The paternalistic "doctor knows best" model of medicine has been "replaced by drug manufacturers who urge the use of their drugs in mass-market print and television advertisements targeted directly at the public." *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 732 (D. Minn. 2005). The FDA's 1997 guidance on the use of direct-to-consumer advertising opened the floodgates of pharmaceutical advertising.[7] Lilly and other drug companies invest in consumer advertising for a reason: it moves product. Lilly's Cymbalta ad campaigns have been remarkably successful; its "Depression hurts. Cymbalta can help." campaign generated a "6-1 return on investment—virtually unheard of among top drug advertisers."[8]

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[7] *See Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245, 1263 (N.J. 1999) (discussing impact of FDA's 1997 guidance).

[8] ER451.

By 2005, doctors writing in the Journal of the American Medical Association observed that consumer advertising, and resulting brand-specific requests from patients, had a "profound effect on physician prescribing" related to depressive symptoms.[9] These doctors observed that "[i]f patients can sway physicians to prescribe drugs they would otherwise not consider, physicians may not be the stalwart intermediary that the law assumes."[10]

The proliferation of consumer advertising was not the only major change in the healthcare industry. The Internet has altered the way consumers access information about treatment options—the WebMD phenomenon.[11] *See State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 907 (W. Va. 2007) (discussing the outdatedness of the LID in light of "the development of the internet as a common method of dispensing and obtaining prescription drug information."); *Rimbert v.*

[9] ER481.
[10] ER487.
[11] Lilly has aggressively utilized this change to promote Cymbalta as well. For example, Lilly sponsored a quiz on WebMD that informed quiz takers that they were at risk for depression and should talk to their doctors about Cymbalta *no matter how they answered the questions*. ER458. The quiz was so misleading that Senator Charles Grassley called for an investigation into the financial ties between Lilly and WebMD. ER461.

Eli Lilly & Co., 577 F. Supp. 2d 1174, 1218 (D.N.M. 2008) (same). Lilly acknowledged this in a 2005 press release: "More than ever, we know that patients are actively seeking information about diseases and treatments, asking questions, evaluating information, and making choices."[12]

Thus, in contrast to the medical landscape of yesteryear, now "neither the drug manufacturers nor the patient totally relies on the intermediary." *Rimbert*, 577 F. Supp. 2d at 1218. As a result of both consumer advertising and the adoption of the Internet as a source of medical information, "[t]he manufacturer and the patient are communicating directly and the consumer is relying on that direct communication." *Id.*

Whether or not the LID is outdated as a tort defense—an issue not before the Court—it has no place shielding drug companies from liability under remedial statutes intended to prevent deceptive conduct toward consumers. In fact, "[t]his new drug-marketing environment calls out for *enhanced* consumer protection," not less. *Witczak*, 377 F. Supp. 2d at 732 (emphasis added). Nowadays promotion of prescription

[12] ER478.

healthcare products looks much like promotion of other products.[13] If Lilly wants the benefit of advertising its products directly to consumers, it must abide by consumer protection laws like any other business. *See, e.g.*, *Karlin v. IVF Am., Inc.*, 712 N.E.2d 662, 668 (N.Y. 1999) (when medical providers "choose to reach out to the consuming public at large in order to promote business . . . they subject themselves to the standards of an honest marketplace secured by General Business Law §§ 349 and 350."). With the benefit goes the burden.

B. There is no statutory basis for adopting the learned intermediary defense.

Liability for statutory violations depends on the elements of the statutes themselves and the existence of any statutory affirmative defenses. Here, there is simply no statutory basis for importing the LID as an affirmative defense to consumer protection claims.

An Oregon case illustrates one state supreme court's analysis—and rejection—of the LID's application to a statutory regime. *Griffith v. Blatt*, 51 P.3d 1256 (Or. 2002). The appellate court had found that the

[13] In terms of its U.S. consumer advertising spending, Lilly is on par with companies like Nestlé and General Mills. *100 Leading National Advertisers 2012*, Advertising Age, June 25, 2012, at 16. In 2011, Lilly spent more on advertising than PepsiCo and Nike. *Id.*

LID shielded a defendant from liability under Oregon's Products Liability Act. *See id.* at 1261. The Oregon Supreme Court, however, looked to the statutory text and the legislature's stated intent regarding construction of the statute and concluded there was no statutory basis for the LID as a defense to strict liability. *Id.* at 1262. The lower court "failed to acknowledge that Oregon statutes, not the common law, govern." *Id.* at 1261. This was echoed by a Missouri court considering claims under the MPA involving misrepresentations about a prescription drug, as it observed that the LID "is a *common law* defense and may not apply to a *statutory* claim, particularly one based upon a remedial statute designed to protect the consuming public." *Plubell v. Merck & Co.*, No. 04-235817-01, 2008 WL 4771525, at n.5 (Mo. Cir. Ct. June 12, 2008).

The Missouri Supreme Court confirmed this reasoning a year later, rejecting the application of another common law defense, the voluntary payment doctrine, to claims under the MPA. *Huch v. Charter Commc'ns, Inc.*, 290 S.W.3d 721, 725 (Mo. 2009) (en banc). It explained that "[b]ecause of the act's broad scope and the legislature's clear policy to protect consumers, certain legal principles are not available to defeat

claims authorized by the act." *Id.* Likewise here, incorporating the affirmative LID tort defense undermines the MPA's intended breadth and remedial purpose.

Applying the LID to consumer protection statutes would effectively remove prescription drugs from the oversight of consumer protection legislation, because the LID shifts the focus away from consumers to the intermediary. In other words, drug companies could not be held legally accountable for what they tell consumers. But that is not the law. The statutes of the four states at issue contain no such exception. New York's highest court, for example, rejected a categorical exclusion of medical services and products from the NYPCA, holding that "[t]hese statutes on their face apply to *virtually all economic activity*, and their application has been correspondingly broad[.]" *Karlin*, 712 N.E.2d at 665 (emphasis added) (footnote omitted); *accord Darviris v. Petros*, 812 N.E.2d 1188, 1193 (Mass. 2004) (confirming that "the entrepreneurial and business aspects of providing medical services" are within the scope of Ch. 93a). The statutes' purposefully broad reach "'provide[s] needed authority to cope with the numerous, ever-changing types of false and deceptive business practices which plague

consumers.'" *Karlin*, 712 N.E.2d at 665 (citations omitted); *see also Baldassari v. Pub. Fin. Trust*, 337 N.E.2d 701, 706 (Mass. 1975) (Ch. 93a § 9 was "designed to meet a pressing need for an effective private remedy."). Because these causes of action are the creation of statute, they are "therefore, sui generis," and "not subject to the traditional limitations of preexisting causes of action." *Slaney v. Westwood Auto, Inc.*, 322 N.E.2d 768, 779 (Mass. 1975).[14] The independent legal remedies provided by these statutes are separate from tort remedies—and, likewise, tort defenses.

C. The district court ignored pertinent state law and relied on inapposite cases from outside jurisdictions.

The district court held that the four states would apply the LID to their respective consumer protection statutes without analyzing the statutes themselves or state precedent, notwithstanding that it understood its task was "'to predict how the [relevant state] Supreme

[14] *See also, e.g.*, *Bank of the W. v. Superior Court*, 833 P.2d 545, 553 (Cal. 1992) ("[T]o state a claim under the [UCL] one need not plead and prove the elements of a tort."); *Huch*, 290 S.W.3d at 724 ("The legislature intended [MPA] section 407.020 to supplement the definitions of common law fraud in an attempt to preserve fundamental honesty, fair play and right dealings in public transactions.") (citation omitted).

Court would decide the issue.'" ER41 (alterations in original) (quoting *Burlington Ins. Co. v. Oceanic Design & Const., Inc.*, 383 F.3d 940, 944 (9th Cir. 2004)). To do this, a court "must ascertain state law from all the available data." *Katz v. Children's Hosp. of Orange Cty.*, 28 F.3d 1520, 1529 (9th Cir. 1994), as amended (July 26, 1994) (citations omitted).

Although the district court asserted that the parties had not identified a state supreme court or appellate court decision specifically addressing the LID's application to consumer statutes, ER41, Plaintiffs relied on an appellate decision from Missouri that did just that. *See* D. Ct. Dkt. 66 (citing *Plubell v. Merck & Co.*, 289 S.W.3d 707 (Mo. Ct. App. 2009)). *Plubell* was precisely on point: the plaintiffs brought claims under the MPA involving alleged misrepresentations about serious health risks from a prescription drug. The Missouri Court of Appeals rejected the defendant's argument that the LID applied to plaintiffs' claims, explaining that "individualized evidence of each physician's and consumer's reliance on the misrepresentation is not required." *Plubell*, 289 S.W.3d at 714. Because a learned intermediary's subjective considerations are not relevant to MPA claims, the LID cannot provide

an affirmative defense. But rather than analyzing *Plubell* to predict how the Missouri Supreme Court would rule on the application of the LID to the MPA, *see Katz*, 28 F.3d at 1529, the district court ignored it. The district court's summary judgment order also ignored *Krueger v. Wyeth, Inc.*, No. 03-2496, 2011 WL 8971449 (S.D. Cal. Mar. 30, 2011), which rejected the defendant's injecting the LID into prescription drug claims under California's consumer protection statutes.

Instead, the district court relied exclusively on federal court decisions from outside jurisdictions—all of which were individual personal injury actions. None involved consumer protection class actions. The district court was permitted, of course, to consider "'well-reasoned decisions from other jurisdictions.'" ER41 (quoting *Burlington Ins. Co.*, 383 F.3d at 944). But individual personal injury actions are largely inapposite and some of them cannot be called "well-reasoned." For example, the district court relied on the discussion of the NYCPA in *Colacicco v. Apotex*[15]—despite the fact that in its prior ruling, it held that the *Colacicco* court got it wrong. Compare ER42-43 and ER56

[15] *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), *aff'd*, 521 F.3d 253 (3d Cir. 2008), *cert. granted, judgment vacated*, 556 U.S. 1101 (2009).

("declin[ing] Defendant's invitation to hold that the learned intermediary doctrine bars consumer protection claims," which is precisely what *Colacicco* held).

The district court also relied heavily on a nearly two-decade-old order from a federal court holding all of the plaintiff's causes of action "collapse[d]" into a failure-to-warn claim in tort. *In re Norplant Contraceptive Prods. Liab. Litig.*, 955 F. Supp. 700, 709 (E.D. Tex. 1997). Quoting *Norplant*, the district court reasoned that a plaintiff should not be able to avoid the LID by "casting what is essentially a failure to warn claim under a different cause of action," ER41, and therefore treated Plaintiffs' claims like tort claims. But Plaintiffs here did not plead failure-to-warn claims like the plaintiffs in *Norplant*, and "the party who brings a suit is master to decide what law he will rely upon." *The Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913). Neither Lilly nor the district court should be permitted to rewrite Plaintiffs' claims. In the absence of an express merger provision,[16] there is no reason for statutory consumer protection claims to "collapse" into tort claims.

[16] *E.g.*, N.J. Stat. Ann. § 2A:58C-1(b)(3).

By relying only on tort cases from other federal courts and ignoring state court opinions and the statutes themselves, the district court simply did not consider "all the available data." *Katz*, 28 F.3d at 1529 (citation omitted). The district court erred as a matter of law by importing an affirmative tort defense into these four states' remedial consumer protection statutes.

IV. The District Court Abused Its Discretion in Denying Class Certification.

In the same order in which it held that Plaintiffs' statutory claims were subject to a tort defense, the district court speculated that class actions involving prescription drugs were impossible and then ordered Plaintiffs to move immediately for class certification without discovery. ER44-45. Plaintiffs thereafter proposed three different ways that their claims could be certified: first, four statewide classes seeking actual damages for consumers in California, Massachusetts, Missouri, and New York under Rule 23(b)(3); second, two statewide classes seeking statutory damages only for Massachusetts and New York consumers under Rule 23(b)(3); and third, liability-only issue classes under Rule 23(c)(4). The district court rejected all three approaches in a decision

rife with legal and factual errors and which contradicted the fundamental purpose of Rule 23.

A. The district court abused its discretion by forcing Plaintiffs to move for class certification without discovery.

For all three denials of class certification the district court abused its discretion by forcing Plaintiffs to move for class certification without needed (and repeatedly requested) discovery. This Court has recognized "the unremarkable proposition that often the pleadings alone will not resolve the question of class certification and that some discovery will be warranted." *Vinole v. Countrywide Home Loans, Inc.*, 571 F.3d 935, 942 (9th Cir. 2009). Failing to allow precertification discovery where it is necessary to demonstrate the propriety of a class action is an abuse of discretion, particularly in the context of repeated requests. *See Perez v. Safelite Grp. Inc.*, 553 F. App'x 667, 668-69 (9th Cir. 2014).

The district court's management of the case further stacked the deck against Plaintiffs. After Lilly failed to provide evidentiary support for its opposition to class certification, the district court allowed Lilly to supplement it, and after ordering a third round of briefing, allowed

limited discovery at Lilly's request on Plaintiffs' damages model. ER35-37.

Although a district court has discretion to manage the conduct of litigation, the court here abused that discretion when it denied class certification in part because "[t]he parties have already engaged in substantial discovery, including expert disclosures." ER31. This assertion is simply false.

Expert disclosures were *never* made under Rule 26(a)(2)(A), expert reports were *never* created or exchanged under Rule 26(a)(2)(B), and Lilly only produced nine documents. Discovery was anything but "substantial." The district court's refusal to certify a class for lack of evidence, *see* ER31, 12, after preventing Plaintiffs from seeking that evidence was an abuse of discretion. *See Perez*, 553 F. App'x at 669.

B. With respect to classes seeking actual damages, the district court's rulings on predominance and superiority were based on errors of law and fact.

The district court denied certification of classes seeking actual damages because it ruled that, with respect to both damages and causation, Plaintiffs failed to satisfy Rule 23(b)(3)'s predominance requirement.

The district court made three errors in assessing whether predominance was satisfied as to damages. First, the district court improperly evaluated the merits of Plaintiffs' proposed model. Second, in its improper merits inquiry, the district court made additional legal and factual errors. Third, the district court erred in ruling that Plaintiffs' measure of damages was not tied to their liability theory.

With respect to causation, the district court failed to apply the objective standards of the consumer protection statutes at issue.

The district court also applied the wrong standard when it again focused on damages in its analysis of superiority.

1. The district court improperly evaluated the merits of Dr. Hay's proposed damages model.

The district court abused its discretion by going beyond its gatekeeper function to adjudicate the merits of Dr. Hay's damages model, stating that "the court must also assess the persuasiveness of the evidence." ER19. But as the Supreme Court recently clarified, "[o]nce a district court finds evidence to be admissible, its persuasiveness is, in general, a matter for the jury." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1049 (2016). "Rule 23 grants courts no license to engage in free-ranging merits inquiries at the certification

stage. Merits questions may be considered to the extent—*but only to the extent*—that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1194-95 (2013) (emphasis added).

When evaluating class certification, the district court's job is to rigorously examine whether the proposed method for calculating damages "stemmed from the defendant's actions that created legal liability," not to weigh the model's merits. *Leyva v. Medline Indus. Inc.*, 716 F.3d 510, 514 (9th Cir. 2013). Accordingly, the district court applied the incorrect legal standard and abused its discretion by engaging in a free-ranging merits analysis of Dr. Hay's proposed damages model.

2. While improperly considering the merits of Dr. Hay's model, the district court made additional legal and factual errors.

Compounding its error of considering the persuasiveness of Dr. Hay's damages model, the district court erred by rejecting it based on errors of law and fact: concluding that an inefficient market prevents damages calculations, failing to consider how the value determined

through Plaintiffs' proposed analysis could be used to estimate damages, and taking sides in a factual dispute between experts.

(a) The district court erred by ruling that damages cannot be determined in an inefficient market.

The district court held that Dr. Hay's damages model was "highly flawed" because it did not tether a consumer's estimated damages to the price, or "fair market value," of Cymbalta. ER22.[17] The district court erroneously reasoned that the model would not consider the market's supply side and therefore a consumer could "recover based on consumers' willingness to pay irrespective of what would happen in a functioning market (i.e. what could be called sellers' willingness to sell)." ER22. But in fact, Plaintiffs' damages model is appropriate for an inefficient market; there is no legal basis for excluding products sold in inefficient markets from consumer protection legislation; and the law allows estimation of damages.

[17] The district court defined fair market value as "the 'price that a seller is willing to accept and a buyer is willing to pay on the open market and in an arm's-length transaction; the point at which supply and demand intersect.'" (citations omitted). ER20.

In order to explain how the district court erred, Plaintiffs must first explain their damages model. Plaintiffs allege that they sustained economic harm by purchasing Cymbalta when Lilly omitted material information regarding the frequency, severity, and duration of Cymbalta withdrawal. ER128-30. Accordingly, Plaintiffs' damages are the difference in value between Cymbalta as represented versus Cymbalta as it actually was. "Value," here, is defined as the "measure of the benefit a typical consumer believes they will obtain by use or ownership of the product." ER309. In an efficient market, price is a proxy for a product's value; for brand-name prescription drugs, however, the link between price and value is more attenuated. ER310-11, 1660-62. This is because drug manufacturers enjoy a lawful monopoly over a brand-name drug until it goes generic. *See Kaiser Found. Health Plan, Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1044 (9th Cir. 2009).

So, instead of using price as a proxy for value, Dr. Hay, a pharmaceutical economist, proposed the alternative of using "conjoint analysis" to ascertain the value of Cymbalta's withdrawal attribute without reference to price. ER311, 1660-62. Conjoint ("***con***sider

jointly") analysis is a statistical technique used in market research to objectively determine the value consumers assign to specific product attributes. ER384, 1662. Conjoint analysis conceptualizes a product as a bundle of attributes and uses statistical modeling to assess how "consumers make relational choices about products based upon the product's features and functionality." ER384. Through web-based surveys, consumers choose between products based on various attribute configurations. Then, the aggregated data is used to estimate how the value of a particular attribute affects the value of the product as a whole. ER1671-74.

Dr. Hay proposed conducting a conjoint study to estimate the difference in value between Cymbalta with a 1% or greater withdrawal risk and Cymbalta with a 44% or greater withdrawal risk. ER311, 1661-62. The result could be expressed as an absolute dollar figure, capped at a consumer's actual out-of-pocket expenses, or as a percentage of the overall value of the product (a "refund ratio"), multiplied against out-of-pocket expenses. ER1674. This model would thus allow Dr. Hay to both ascertain an objective measure of the

relative value of the omitted withdrawal risk and to calculate damages based on out-of-pocket expenses.

The logical extension of the district court's ruling is that damages for a consumer protection violation can *only* be calculated by reference to the product's fair market value. This reasoning would effectively eliminate consumer claims for any product sold in an inefficient marketplace because damages for such products could not be tethered to fair market value. This does not comport with the broad construction given to the consumer protection laws of Plaintiffs' states, which do not exempt pharmaceutical products or any other goods sold in inefficient markets. *See* Section II.B, *supra* (discussing intended breadth of the relevant consumer protection statutes). These statutes were intended to be construed broadly, and as New York's high court held, cover "virtually all economic activity," *Karlin*, 712 N.E.2d at 665—regardless of whether the product is sold in an efficient or inefficient market.

Furthermore, it has long been the law that damages need not "be calculated with absolute exactness." *Eastman Kodak Co. of N.Y. v. S. Photo Materials Co.*, 273 U.S. 359, 379 (1927). Instead, "[i]t is sufficient if a reasonable basis of computation is afforded, although the result be

only approximate." *Id.* Moreover, "[t]he damages inquiry does not allow a defendant to benefit from the scope of its wrongdoing; this is why '[e]ven speculation has its place in estimating damages, and doubts should be resolved against the wrongdoer.'" *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, 49-50 (1st Cir. 2013) (endorsing the use of statistical analysis to calculate damages in suit based on marketing fraud of prescription drug). "Any other rule would enable the wrongdoer to profit by his wrongdoing at the expense of his victim." *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 124 (1969).

In the end, there is no dispute that conjoint analysis is a reliable scientific method for estimating how consumers value a particular product attribute. Lilly's expert conceded as much. ER1717 ("Q. [I]s it then true that conjoint analysis can predict how, on average, all consumers value a particular attribute? A. If everything was done correctly, yes."). Marketing analysts "have used conjoint analysis since the early 1970's to determine the values consumers ascribe to specific attributes of multi-attribute products." *In re ConAgra Foods, Inc.*, 90 F.

Supp. 3d 919, 1026 (C.D. Cal. 2015).[18] In fact, Lilly regularly uses conjoint analysis to assess attributes of its products, including Cymbalta. ER1677-85 (discussing, in detail, several conjoint studies conducted by Lilly).[19]

The relevant question is whether conjoint analysis can provide a reasonable basis for a jury to calculate damages. *See Tyson*, 136 S. Ct. at 1046 (statistical analysis appropriate to prove damages for class provided "each class member could have relied on that [calculation] to establish liability if he or she had brought an individual action."). Plaintiffs could present the results of the conjoint study at trial and, from those results, a jury could return a verdict that would fairly estimate individual as well as classwide damages. The district court

[18] While the district court relied on *In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 552 (C.D. Cal. 2014), throughout its denial of class certification and specifically to discount the use of conjoint analysis in estimating damages in a consumer class action, ER24-25, 28, 30, the *ConAgra* court reconsidered its position six months later and endorsed the use conjoint analysis to calculate damages. *See In re ConAgra Foods, Inc.*, 90 F. Supp. 3d 919, 1023-30 (C.D. Cal. 2015).

[19] *See also TV Interactive Data Corp. v. Sony Corp.*, 929 F. Supp. 2d 1006, 1020-27 (N.D. Cal. 2013) (conjoint analysis is a valid method for ascertaining how consumers value specific attributes); *Microsoft Corp. v. Motorola, Inc.*, 904 F. Supp. 2d 1109, 1120 (W.D. Wash. 2012) (finding conjoint survey reliable).

erred by rejecting Plaintiffs' damages model because of the inefficient pharmaceutical market.

(b) The district court did not fully consider how the relative value determined through conjoint analysis could be used to estimate damages.

As Dr. Hay explained, relative value determined through conjoint analysis could be used to estimate damages in one of two ways, both of which would tie to the consumer's out-of-pocket expenses: an absolute value or a refund ratio. ER389, 312-13. The district court abused its discretion by failing to adequately consider both approaches.

First, the district court erroneously held that Plaintiffs had abandoned the absolute value approach. In a footnote, the district court stated that "[b]ecause neither party focuses on this measure and because it was seemingly abandoned in Dr. Hay's third declaration, the Court declines to address it." ER21. This is wrong. The absolute value approach was proposed and argued in Dr. Hay's first two declarations and Plaintiffs' supplemental briefing. ER389-90, 312-13, 371. In the third round of briefing, Plaintiffs did not *again* address the absolute value approach because Lilly never challenged it and the district court did not request additional briefing. At no time did Plaintiffs *abandon* it.

The district court's refusal to consider it, thus, was an abuse of discretion. *Parra v. Bashas', Inc.*, 536 F.3d 975, 977-78 (9th Cir. 2008) ("An abuse of discretion occurs when the district court, 'in making a discretionary ruling . . . omits consideration of a factor entitled to substantial weight[.]'") (citation omitted).

Second, the district court did not think it was appropriate to calculate damages based a consumer's out-of-pocket expenses for those consumers who purchased Cymbalta with a co-pay. ER23-24. The district court reasoned that the amount of money a consumer spends for Cymbalta as part of a co-pay does not necessarily represent that consumer's particular valuation of the drug, so basing a refund on out-of-pocket costs for those consumers "does not yield an accurate approximation of the difference between the consumer's subjective valuation of the drug as represented and the drug as actually received." ER23-24.

This criticism should not have prevented class certification, as it can be easily fixed by multiplying the refund ratio against the full price paid for Cymbalta (the consumer's co-pay plus whatever the insurance company paid), with a damages ceiling set at the amount each class

member paid out of pocket. This slight adjustment to the damages calculation would put co-pay consumers in the same position as those who paid full price, while ensuring that co-pay consumers could not recover more than they spent.[20] Dr. Hay's proposal was actually more conservative (to Lilly's benefit), but the damages calculation could be adjusted to address the district court's concern.[21] In any event, neither a refund ratio nor using an absolute value would require any individualized inquiry beyond what is typically done in consumer protection claims involving prescription drugs. *See, e.g.*, *In re Celexa & Lexapro*, 2014 WL 4446464, at *3 (discussing how consumers would be refunded for the antidepressants Celexa and Lexapro based on purchase price).

[20] The proposed absolute value approach was also capped by class members' actual out-of-pocket expenses. *See* ER313.

[21] If the district court's concern is that third-party payors should have been included within the class, then the class definition could be adjusted to include them. For example, in *In re Celexa & Lexapro*, the class consisted of both third-party payors and consumers, and their respective refunds were adjusted according to what they paid. *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, MDL No. 09-2067, 2014 WL 4446464, at *3-4 (D. Mass. Sept. 8, 2014).

(c) The district court improperly took sides in an expert dispute.

The district court also rejected Dr. Hay's model on the basis that it suffered from "serious methodological flaws." ER24. Specifically, it took issue with Dr. Hay proposing to conduct a survey in 2014 to estimate preferences for consumers who purchased Cymbalta as far back as 2004. *Id.* But Dr. Hay explained that there is no reason to believe that consumers valued withdrawal risk differently in 2004 than today and pointed out that Lilly's expert had testified in prior litigation that aging of data was not a problem. ER1704-06. Dr. Hay then refuted, point by point, each criticism leveled by Lilly's expert. ER1706-08. But without an evidentiary hearing and based on nothing more than competing expert declarations, the district court sided with Lilly's expert, characterizing Dr. Hay's statements as "bald assertions" and "unpersuasive" and opining that certain events since 2004 could be "potentially significant to consumer valuation." ER24.

This was an abuse of discretion. "[T]he reasonableness of the assumptions underlying the experts' ... analysis, [or] criticisms of an expert's method of calculation [are] matter[s] for the jury's consideration in weighing that evidence." *Dorn v. Burlington N. Santa*

Fe R.R., 397 F.3d 1183, 1196 (9th Cir. 2005) (quoting *Humetrix, Inc. v. Gemplus S.C.A.,* 268 F.3d 910, 919 (9th Cir. 2001)). As this Court held in *Dorn*, "the '[a]uthority to determine the victor in such a 'battle of expert witnesses' is properly reposed in the jury.'" 397 F.3d at 1196 (quoting *Humetrix,* 268 F.3d at 919). Lilly's expert's criticism of Dr. Hay's conjoint analysis (a methodology Lilly itself uses) is for cross-examination and not for a district court to usurp the role of the jury.

3. The district court erred by holding that Plaintiffs' damages model was not tied to their liability theory.

The district court concluded that Plaintiffs "failed to present a method of calculating damages that is tied to their theory of liability." ER25. But the district court got it wrong, thereby abusing its discretion. Plaintiffs' damages methodology was directly tied to their liability theory, because it would determine the damages sustained by the reasonable consumer, which is the standard for liability under the relevant consumer statutes.

In *Comcast Corp. v. Behrend*, the Supreme Court held that "any model supporting a 'plaintiff's damages case must be consistent with its

liability case.'"[22] 133 S. Ct. 1426, 1433 (2013). The Court emphasized that "[t]he first step in a damages study is the translation of the *legal theory of the harmful event* into an analysis of the economic impact *of that event*." *Id.* at 1435 (citation omitted). Here, the legal theory of Lilly's deception—liability under each consumer protection statute—turns on whether Lilly's omission was material to a reasonable consumer. Under *Comcast*, Plaintiffs' damages must be measured by reference to the alleged statutory violations, and therefore the correct measure of damages is based on the objective reasonable-consumer standard.

Dr. Hay's damages model measures precisely that. It analyzes the economic impact of the harmful event: Lilly's material omission. Dr. Hay's model would determine the damages incurred by the reasonable consumer using conjoint analysis to determine the total value that the

[22] *Comcast* did not change the fact that individualized damages do not defeat class certification. *See Pulaski & Middleman, LLC v. Google, Inc.*, 802 F.3d 979, 988 (9th Cir. 2015) ("[*C*]*omcast* did not hold that Rule 23(b)(3) requires a classwide basis for damages calculation."), *petition for cert. filed*, 84 U.S.L.W. 3500 (U.S. Mar. 1, 2016) (No. 15-1101). Instead, *Comcast* stands for the unremarkable proposition that "plaintiffs must be able to show that their damages stemmed from the defendant's actions that created the legal liability." *Leyva v. Medline Indus. Inc.*, 716 F.3d 510, 514 (9th Cir. 2013).

average consumer would have lost due to Lilly's omission. ER1673-74. An average consumer is reasonable by definition.[23] Whether this value determination is expressed as an absolute dollar amount or a ratio, it would then be applied to each class member's actual out-of-pocket costs in order to determine the damages that a reasonable consumer in each class member's position incurred. This model would work on an individual basis as well as classwide. *See Tyson*, 136 S. Ct. at 1046-47. And because this measure of damages flows from Plaintiffs' substantive theory of liability, it strictly adheres to the Supreme Court's decision in *Comcast*.

The district court misunderstood the objective standard for liability under the consumer protection statutes at issue and abused its discretion in holding that Plaintiffs' damages model was not tied to their liability theory. *See Cooter & Gell v. Hartmarx Corp.*, 496 U.S.

[23] *See Arroyo v. United States*, 656 F.3d 663, 673 (7th Cir. 2011) (Posner, J., concurring) ("As a practical matter what used to be called the "reasonable man" concept in tort law, now unsexed to conform to modern sensibilities, means the average person . . . ."); *N.C. ex rel. Cooper v. Tenn. Valley Auth.*, 615 F.3d 291, 310 (4th Cir. 2010) (equating "average person" with "ordinary reasonable man" (citation omitted)).

384, 405 (1990) ("A district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law[.]").

4. The district court applied the wrong causation standard.

The district court also misunderstood the statutes' objective standards when it held that individual questions would predominate with respect to causation. The district court doubted "that classwide proof of causation and injury is appropriate in this case[,]" ER25, reasoning that "the causal effect of Lilly's alleged misstatements will differ widely between individuals." ER27. According to the district court, it is "inappropriate to assume that because the alleged misstatement would be important to a reasonable person that it must have induced Plaintiffs to purchase Cymbalta[.]" ER27. But none of the relevant statutes require a showing that the misrepresentations or omissions induced a purchase.

In Missouri, a causal relationship between the alleged omissions and a plaintiff's *purchase* is not required. *Plubell*, 289 S.W.3d at 714. A plaintiff need only show a connection between the deception and the *loss*. *Id.* Similarly in Massachusetts and New York, there is no requirement for individual reliance—a plaintiff need only show that a

consumer's loss was the result of a deceptive practice. *Tyler v. Michaels Stores, Inc.*, 984 N.E.2d 737, 745 (Mass. 2013); *Koch v. Acker, Merrall & Condit Co.*, 967 N.E.2d 675, 676 (N.Y. 2012); *Stutman v. Chem. Bank*, 731 N.E.2d 608, 612-13 (N.Y. 2000). And, in California, although class representatives must establish that they personally relied on the misrepresentation or omission in making the purchasing decision to have standing, *see In re Tobacco II Cases*, 207 P.3d 20, 39-40 (Cal. 2009), "[c]ausation, on a classwide basis, may be established by *materiality*." *Stearns v. Ticketmaster Corp.*, 655 F.3d 1013, 1022 (9th Cir. 2011) (citations omitted).

Thus, to establish causation in these four states, Plaintiffs need only show that the omission was objectively material, i.e., that a reasonable consumer would have considered the information important in making a purchasing decision—an issue ideally suited for class resolution. *In re Steroid Hormone Prod. Cases*, 104 Cal. Rptr. 3d 329, 338 (Ct. App. 2010); *Aspinall v. Philip Morris Cos.*, 813 N.E.2d 476, 488 (Mass. 2004); *Hess v. Chase Manhattan Bank, USA, N.A.*, 220 S.W.3d 758, 773 (Mo. 2007); *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A.*, 647 N.E.2d 741, 745 (N.Y. 1995). Plaintiffs

need not show that Lilly's deception induced each class member's decision to purchase Cymbalta. The district court's claim—that individual issues relating to reliance and causation precluded class certification—was unfounded. The district court applied the wrong legal standard.

5. The district court improperly considered damage calculations as part of its superiority analysis.

Of the four elements a court considers in assessing superiority, *see* Fed. R. Civ. P. 23(b)(3)(A)-(D), the district court held that three weighed in favor of class certification, but that the "fourth factor—the likely difficulties in managing a class action—strongly counsels against certification." ER29. The district court reasoned that the need to compute individual damages would make a class action "unmanageable." ER29. But the district court erred by considering damage calculations as part of the manageability of the proposed class actions. *See Leyva*, 716 F.3d at 515 (holding that a "district court [ ] abused its discretion when it based its manageability concerns on the need to individually calculate damages."). This Court has repeatedly held "that damage calculations alone cannot defeat class certification." *Pulaski*, 802 F.3d at 987 (citing *Leyva*, 716 F.3d at 513-14); *Yokoyama v.*

Midland Nat'l Life Ins. Co., 594 F.3d 1087, 1094 (9th Cir. 2010). A district court therefore applies the "wrong legal standard when it conclude[s] that a class action [is] not the superior method for resolving the putative class members' claims" based solely on the need to calculate damages, particularly when the district court has "acknowledged that certification was superior" under the other three factors. *Leyva,* 716 F.3d at 514. By basing its ruling on an erroneous view of the law, the district court abused its discretion. *See id.* at 515 (quoting *Cooter,* 496 U.S. at 405).

C. The district court abused its discretion by declining to certify classes seeking statutory damages.

In the alternative to certifying four statewide classes seeking actual damages based on conjoint analysis, Plaintiffs sought to certify two statewide classes seeking statutory damages. In Massachusetts and New York, plaintiffs can receive a statutorily prescribed minimum—$25 in Massachusetts and $50 in New York—if actual damages are not ascertainable. Mass. Gen. Laws ch. 93A; N.Y. Gen. Bus. Law § 349(h). In order to do so, plaintiffs must establish liability under the elements of the statutes, each of which requires proving a separate harm distinct from the statutory violation. *See Tyler*, 984 N.E.2d at 746 n.17; *Oswego*

Laborers', 647 N.E.2d at 745. This harm may be economic or non-economic, and any "harm worth more than a penny" will suffice. *See Tyler*, 984 N.E.2d at 746 n.20; *Oswego Laborers'*, 647 N.E.2d at 745.

The district court acknowledged that, as Plaintiffs sought statutory damages only, "there is no question that they have adequately proposed a damages model." ER10. But the district court held that Plaintiffs could not establish classwide injury, commenting that "Plaintiffs apparently assume that though class members were affected to different degrees, each was affected to some degree." ER12. In fact, Plaintiffs can establish "some degree" of harm in at least three ways: (1) through a classwide presumption of harm because Lilly misleadingly marketed Cymbalta as safer than it actually was; (2) through use of conjoint analysis; or (3) through a price premium. Under any of these approaches, common questions predominate on the merits.

1. Lilly harmed the class by subjecting consumers to an increased risk of withdrawal.

Under both New York and Massachusetts law, the harm caused by the deceptive practice may be non-pecuniary harm. Examples of non-pecuniary harm include tracking consumers' browsing history without

their knowledge,[24] impairing consumers' right to prevent or minimize the disclosure of their medical information,[25] unlawfully acquiring consumers' personal information and using the information for defendant's own business purposes,[26] and exposing consumers to the risk of paying more than actually owed.[27]

Here, subjecting consumers to an increased risk of serious withdrawal symptoms without their knowledge is an actual harm warranting statutory damages. Moreover, a product that is less safe than it was represented is presumed to be worth less, thereby establishing—without quantifying—actual harm. *See Aspinall v. Philip Morris USA Inc.*, No. 98-6002, 2015 WL 9999126, at *4 (Mass. Super. Ct. Aug. 11, 2015) ("[a] claim that the product purchased was less safe than the product advertised" is sufficient to establish harm). New York and Massachusetts class members would therefore be entitled to statutory damages simply upon showing that Lilly minimized the risk

[24] *Bose v. Interclick, Inc.*, No. 10-9183, 2011 WL 4343517, at *8-9 (S.D.N.Y. Aug. 17, 2011).
[25] *Anonymous v. CVS Corp.*, 728 N.Y.S.2d 333, 340 (2001).
[26] *Tyler*, 984 N.E.2d at 746.
[27] *Lannan v. Levy & White*, --- F. Supp. 3d ----, No. 14-13866, 2016 WL 2937455, at *12 (D. Mass. May 11, 2016).

of Cymbalta withdrawal. However, as discussed below, Plaintiffs proposed two other ways to establish actual economic loss caused by Lilly's deceptive conduct.

2. Plaintiffs could use Dr. Hay's proposed conjoint analysis to show that consumers sustained economic loss.

The non-pecuniary harm of an increased risk of withdrawal symptoms is an actual harm and sufficient to entitle New York and Massachusetts consumers to statutory damages. But Plaintiffs' proposed conjoint analysis provides another, alternative way to show the existence of actual economic harm, regardless of whether it is viewed as an appropriate means of quantifying that harm. The district court dismissed this approach as measuring "a seemingly subjective injury," ER11, but that is not correct. Conjoint analysis would result in an objective measure: the difference in value between Cymbalta as represented and Cymbalta as it actually was for the average consumer. And in disregarding this approach based on its previous rejection of conjoint analysis as a damages model, the district court failed to consider the distinct legal issues raised by proposed statutory-damages classes.

In its previous order denying class certification, the district court stated:

> Plaintiffs fail to justify using the average consumer's willingness to pay to define injuries classwide. It is unclear to the Court why any individual is harmed when she purchases a product that the average person (but not necessarily the purchaser) subjectively overvalues because of a misrepresentation.

ER27. This criticism misses the point. In any consumer class action involving the sale of a misrepresented product, some consumers will not care about the alleged misrepresentation or find the misrepresentation material. But the underlying statutes do not require plaintiffs to prove that the misrepresentations were material to all consumers, only that they were material to a reasonable consumer, i.e., the average consumer.

Moreover, the district court's analysis confuses the existence of harm with the amount of damages. The district court compared using Dr. Hay's conjoint analysis to prove economic harm "to relying on proof of the personal injuries incurred by the average car accident victim to show that a particular car accident caused that same amount of harm to a particular victim." ER28. Not true. The "amount of harm" is relevant to actual damages. But the mere existence of harm is different. The

district court—its erroneous conclusions about calculating actual damages with conjoint analysis notwithstanding—should have recognized that conjoint analysis could establish that the attribute of low withdrawal risk had some value to the average consumer, and that therefore each member of the class sustained "harm worth more than a penny" by purchasing Cymbalta with its undisclosed high withdrawal risk. See *Tyler*, 984 N.E.2d at 746 n.20 (consumers harmed by receiving unwanted marketing materials); *Belfiore v. Procter & Gamble Co.*, 311 F.R.D. 29, 69 (E.D.N.Y. 2015) ("[I]f Freshmates are found to be not 'flushable,' then all consumers were injured.").

Thus, even if the dollar amount of that injury is not calculable—a fact Plaintiffs dispute—consumers in Massachusetts and New York would be entitled to statutory damages having shown that there was some economic loss caused by the statutory violation. The district court did not engage in a rigorous analysis to determine whether conjoint analysis could establish the existence of some degree of economic loss.

3. Plaintiffs could establish classwide economic harm through a price premium theory.

Plaintiffs also proposed using a pricing theory to establish economic loss, positing that Lilly was able to charge a price premium for

Cymbalta because it minimized the risk of withdrawal. Without the benefit of full discovery, Plaintiffs provided the district court with marketing documents obtained through other litigation. ER165-294. One of the documents, a "Cymbalta U.S. Strategic Pricing Study" which Lilly commissioned two years before Cymbalta's launch, indicated that of three "product attributes that justify a premium price over other antidepressants . . . [m]inimization of withdrawal syndrome is also seen as important." ER260. This was evidence that Lilly was able to sell Cymbalta at a higher price by minimizing the risks of withdrawal, even if the exact amount of that price premium for each class member cannot be calculated.

The district court rejected this as a "fraud-on-the-market" approach in an inefficient market, ER11, but Plaintiffs never alleged that the *market* would have set a different price for Cymbalta had Lilly told the truth. Rather, they allege that *Lilly*, not the market, would have set a lower price for Cymbalta had it been forthright about the risks of withdrawal. And Plaintiffs made that assertion based on Lilly's Strategic Pricing Study for Cymbalta, which concluded that a low

withdrawal risk was one attribute that would justify a price premium over competitors. ER260.

The district court acknowledged the pricing study and other marketing documents but declared them "inapt," reasoning that they did not show "(1) that Lilly actually charged a price premium for Cymbalta; (2) that this 'price premium' was a premium over Cymbalta's true value rather than a premium relative to other antidepressants; or (3) that any price premium that Lilly negotiated with third party payors and other entities was passed along to consumers[.]" ER12. These criticisms do not hold water. The first has nothing to do with class certification, but is simply a common fact question that could be answered with discovery—discovery the district court forbade. The second is contradicted by the documents themselves, which specifically discussed pricing relative to Effexor, a competitor drug. ER255. And the third defies well-known facts about the operation of third-party payors. *See Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1364-65 (11th Cir. 2011) (describing how third-party payors pass on the costs of increased drug prices to their beneficiaries).

Whether Lilly charged higher prices for Cymbalta because it minimized the risks of withdrawal is a question that will require discovery, additional litigation, and a jury. But that question can be answered with common proof that could establish that each consumer who purchased Cymbalta suffered *some* economic loss. Such a loss occurs regardless of whether the Plaintiffs can "determine an average price paid for the misrepresentation," and would entitle class members to statutory damages. *Belfiore*, 311 F.R.D. at 70; *see also Smilow v. Sw. Bell Mobile Sys., Inc.*, 323 F.3d 32, 42 (1st Cir. 2003) (same under Massachusetts law). The district court abused its discretion by not fully considering how Plaintiffs' proposed statutory-damages classes differed from the actual-damages classes.

D. The district court's refusal to certify a liability class because of difficulties with establishing damages constituted an abuse of discretion.

Under Rule 23(c)(4), "an action may be brought or maintained as a class action with respect to particular issues." Fed. Rule Civ. P. 23(c)(4). "Even if the common questions do not predominate over the individual questions so that class certification of the entire action is warranted, Rule 23 authorizes the district court in appropriate cases to isolate the

common issues under Rule 23(c)(4)(A) and proceed with class treatment of these particular issues." *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1234 (9th Cir. 1996); *accord In re Nassau Cty. Strip Search Cases*, 461 F.3d 219, 227 (2d Cir. 2006) (endorsing use of Rule 23(c)(4) to certify issue classes); *Pella Corp. v. Saltzman*, 606 F.3d 391, 394 (7th Cir. 2010) ("A district court has the discretion to split a case by certifying a class for some issues, but not others, or by certifying a class for liability alone where damages or causation may require individualized assessments."); *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*, 722 F.3d 838, 860 (6th Cir. 2013) (affirming certification of a liability class under Rule 23(c)(4)). Indeed, district courts should "take full advantage of the provision in Rule 23(c)(4) permitting class treatment of separate issues to reduce the range of disputed issues in complex litigation." *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 426 (4th Cir. 2003) (alterations omitted) (citation omitted); *e.g.*, *Lilly v. Jamba Juice Co.*, 308 F.R.D. 231, 244 (N.D. Cal. 2014) (denying damages class due to predominance but certifying liability-only class).

When the district court ordered Plaintiffs to move for class certification, it remarked that "the question of whether or not the warnings given to doctors, and consumers, were inadequate or misleading may be capable of resolution on a class-wide basis." ER44. This comment prompted Plaintiffs to move, separately, for a liability-only class under Rule 23(c)(4) to determine, on a classwide basis, whether Lilly's omissions regarding Cymbalta were materially misleading under the state laws of Missouri, New York, Massachusetts, and California. In support of the motion, Plaintiffs submitted expert testimony from Professor Alexandra Lahav about how, procedurally and legally, certification and resolution of a liability class would materially advance this litigation as a whole. D. Ct. Dkt. 82.

The district court, however, refused to certify the liability class, holding that "certification of an issue class would not advance the resolution of this litigation" because "Plaintiffs fail to show that damages can be determined even on an individual basis once liability is decided." ER30. This was the *wrong* standard, because the inability to ascertain damages is not a valid ground to deny certification of an issue class. *Jimenez v. Allstate Ins. Co.*, 765 F.3d 1161, 1167 (9th Cir. 2014),

cert. denied, 135 S. Ct. 2835 (2015). "So long as the plaintiffs were harmed by the same conduct, disparities in how or by how much they were harmed did not defeat class certification." *Id.* at 1168. The district court's refusal to certify an issue class based on the inability to calculate damages is "a *per se* abuse of discretion." *Id.* at 1167.

The district court acknowledged that the "Ninth Circuit seems to have implicitly endorsed other Circuits' approach of allowing the certification of liability-only classes where the plaintiff failed to establish predominance on the damages issue." ER30-31 (citing *Rahman v. Mott's LLP*, No. 13-3482, 2014 WL 6815779, at *8 (N.D. Cal. Dec. 3, 2014) and *Jimenez*, 765 F.3d at 1168). However, it attempted to distinguish *Jimenez* and its progeny by reasoning that a liability class is only appropriate when the case is in the early stages and issues surrounding damages "may fall away after liability is determined." ER31 (citations omitted). According to the district court, when there has been considerable discovery, a liability class is unwarranted. ER31. Applying this incorrect rule here, the district court held that the "parties have already engaged in substantial discovery, including expert

disclosures" and that Plaintiffs had "ample opportunity" to "satisfy the requisites of *Comcast*" but "nevertheless failed to do so." ER31.

This argument finds no support in the law or facts. Nothing about Rule 23(c)(4) suggests that liability-only classes are impermissible when there has been substantial discovery. Nor are plaintiffs required to prove damages in seeking a liability-only class. And, even if such a rule existed, substantial discovery had demonstrably not occurred. At the time of the district court's ruling, there had been no Rule 16 scheduling order, no initial disclosures, no discovery, and no answer to the complaint. It was not until the third round of class certification briefing that the district court permitted very limited discovery, which consisted of Lilly producing nine documents and each party taking the deposition of the other's damages expert. The district court's analysis in denying Plaintiffs' motion for a liability class is fraught with factual and legal missteps and warrants reversal.[28]

[28] The district court's holding here is in direct conflict with its own later ruling in *Loritz v. Exide Technologies*, No. 13-2607, 2015 WL 6790247 (C.D. Cal. July 21, 2015) (Wilson, J.). In *Loritz*, the district court acknowledged the viability of issue classes and held that even though "[p]laintiffs fail to present a classwide damages model tied to their theory of liability" this "is not a case where [p]laintiffs failed to put forth *any* admissible evidence establishing that it is possible to

E. The district court's denial of class certification contradicted the fundamental purpose of Rule 23.

The district court recognized that the overriding common question of whether Lilly's conduct was misleading was capable of classwide resolution. ER44. That question will go unanswered without class certification. Lilly engaged in a far-reaching deception about a serious health risk, affecting millions of people but not, in the majority of those cases, in a way that would justify individual litigation. Rule 23 exists just for such cases. "Otherwise defendants would be able to escape liability for tortious harms of enormous aggregate magnitude but so widely distributed as not to be remediable in individual suits." *Butler v. Sears, Roebuck & Co.*, 727 F.3d 796, 801 (7th Cir. 2013) (Posner, J.). The district court's denial of class certification should be reversed.

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calculate the amount of damages tied to their theory of liability." *Id.* at *24. The district court allowed an issue class because plaintiffs did not "utterly fail to show any model for calculating damages," *id.* at *23, and it would be "possible to calculate damages for at least some of the class members—albeit on an individualized basis and possibly using laborious and difficult calculations." *Id.* at *24. Considering the detailed damages model Plaintiffs presented in this case, it is difficult to see how Plaintiffs did not likewise satisfy Rule 23(c)(4).

V. The District Court Abused Its Discretion In Denying Plaintiffs' Motion for Sanctions With No Explanation.

A. Factual Background

While this case was pending, discovery in two personal injury (non-class) cases involving Cymbalta withdrawal was proceeding in the Eastern District of Virginia. *Ali v. Eli Lilly & Co.*, No. 14-1615 (E.D. Va.), and *Hagan-Brown v. Eli Lilly & Co.*, No. 14-1614 (E.D. Va.). There, Lilly produced 123 documents relating to Lilly's market research of Cymbalta. ER604. Within that production were numerous studies conducted by Lilly indicating that the risk of withdrawal was an important attribute in determining the value of Cymbalta, including conjoint studies. *See, e.g.*, ER1683, 1050, 1463-69. *None* of these studies, however, were produced in *this* case, notwithstanding Lilly being ordered to produce "any conjoint analyses performed or funded by Lilly for Cymbalta." ER33.

In July 2015, while Plaintiffs' third motion for class certification was pending, Plaintiffs filed a motion for sanctions, arguing that Lilly violated the district court's order to produce documents showing Lilly's use of conjoint analysis for Cymbalta. In August 2015, the court entered a minute order denying the motion for sanctions insofar as it sought a

default judgment against Lilly. ER6. Then, in October 2015, the district court denied the remaining portions of Plaintiffs' motion for sanctions without explanation. ER5.

B. The district court declined to impose sanctions without making any factual findings.

While it is true that district courts have "broad fact-finding powers" with respect to sanctions and their findings warrant "great deference," *Townsend v. Holman Consulting Corp.*, 929 F.2d 1358, 1366 (9th Cir. 1990), this deference presumes the existence of factual findings by the district court. This Court must know to what it defers. *Id.* Because the district court provided no explanation as to why it denied Plaintiffs' motion for sanctions, this Court cannot be "certain of the district court's reasoning" or "discern whether the district court considered the relevant factors." *Id.*

In the absence of factual findings by the district court, this Court reviews the sanction determination de novo and need not remand. *See Fonseca v. Sysco Food Servs. of Ariz., Inc.*, 374 F.3d 840, 845-46 (9th Cir. 2004). Sanctions are appropriate here because Plaintiffs were harmed by Lilly's withholding of highly relevant documents. For example, Plaintiffs could have used one of the documents to refute

claims by Lilly's experts that physicians did not consider a drug's withdrawal risk important and that disclosing the accurate withdrawal risk would not have affected Cymbalta's price. The withheld documents were directly pertinent to dispositive issues regarding class certification, and the lack of these relevant documents shaped Plaintiffs' motions for class certification. Plaintiffs also would have been able to depose Lilly's conjoint analysis expert using the withheld documents.

Plaintiffs also requested that Lilly be ordered to pay a portion of Plaintiffs' fees and costs associated with the last round of class certification, which focused solely on conjoint analysis and would have been significantly altered by production of the conjoint studies that Lilly withheld. The district court made no findings of fact regarding Lilly's conduct and provided no explanation for declining to impose this limited sanction.

Plaintiffs respectfully request that this Court order Lilly to pay the aforementioned fees and costs as a sanction for its discovery misconduct, which significantly altered Plaintiffs' pursuit of classwide resolution of their claims.

CONCLUSION

The district court's handling of this case was rife with legal and factual errors and procedural abuses. First, the district court eliminated the possibility of injunctive relief by endorsing a draconian view of Article III standing and ignoring Plaintiffs' request to amend to add a class representative still purchasing Cymbalta. The district court then held that four states would apply a tort defense to their remedial consumer protection statutes without analyzing those statutes or state law. Thus treating Plaintiffs' statutory claims like tort claims, the district court predicted that class certification would be impossible.

Although Plaintiffs proposed three different ways to achieve classwide resolution of their claims—four statewide classes under Rule 23(b)(3), supported by a detailed damages model, two state classes seeking statutory damages only, and a liability-only class under Rule 23(c)(4)—the district court rejected all of them. Together, the district court's rulings effectively insulate prescription drug manufacturers from the reach of consumer protection statutes and the class action mechanism.

Lilly minimized the serious withdrawal risks of Cymbalta, which allowed it to sell more product. Its half-truths about Cymbalta withdrawal kept millions of consumers (and their physicians) in the dark. Consumer protection statutes were intended to police precisely this type of conduct: material omissions and misrepresentations in connection with the sale of a product. The district court went to great lengths, procedurally and substantively, to prevent Plaintiffs from obtaining classwide resolution of their claims. Its holdings cannot stand.

Dated: June 1, 2016.

KELLER ROHRBACK L.L.P.

By: *s/ Michael D. Woerner*

Michael D. Woerner
mwoerner@kellerrohrback.com
Alison S. Gaffney
agaffney@kellerrohrback.com
KELLER ROHRBACK L.L.P.
1201 Third Avenue, Suite 3200
Seattle, WA 98101
Tel.: (206) 623-1900
Fax: (206) 623-3384

Juli E. Farris
jfarris@kellerrohrback.com
Khesraw Karmand
kkarmand@kellerrohrback.com
KELLER ROHRBACK L.L.P.
1129 State Street, Suite 8
Santa Barbara, CA 93101
Tel.: (805) 456-1496
Fax: (805) 456-1497

Mark D. Samson
msamson@kellerrohrback.com
KELLER ROHRBACK L.L.P.
3101 N. Central Avenue, Suite 1400
Phoenix, AZ 85012
Tel.: (602) 248-0088
Fax: (602) 248-2822

Michael L. Baum
mbaum@baumhedlundlaw.com
Bijan Esfandiari
besfandiari@baumhedlundlaw.com
R. Brent Wisner
rbwisner@baumhedlundlaw.com
BAUM, HEDLUND, ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Tel.: (310) 207-3233
Fax: (310) 820-7444

Samuel S. Deskin
sam@deskinlawfirm.com
DESKIN LAW FIRM, PLC
16944 Ventura Blvd
Encino, CA 91316
Tel.: (800) 709-8978
Fax: (800) 709-8971

CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because this brief contains 13,997 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that on June 1, 2016, I electronically filed the foregoing with the United States Court of Appeals for the Ninth Circuit by using the Court's CM/ECF system. I certify that all appellate counsel of record to the parties to this appeal are registered with the Court's CM/ECF system. Pursuant to FRAP 25(d)(1)(b), the names of counsel, mailing addresses, and electronic addresses are listed below:

David E. Stanley
Email: dstanley@reedsmith.com
REED SMITH LLP
355 South Grand Ave., Ste. 2900
Los Angeles, CA 90071
(213) 457-8000

Mark H. Lynch
Email: mlynch@cov.com
Michael X. Imbroscio
Email: mimbroscio@cov.com
Phyllis A. Jones
Email: pajones@cov.com
Michael M. Maya
Email: mmaya@cov.com
COVINGTON & BURLING LLP
One City Center
850 Tenth Street, NW
Washington, DC 20001
(202) 662-6000

Counsel for Defendant-Appellee Eli Lilly and Company

By: s/ *Michael D. Woerner*
Michael D. Woerner